

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P.,	)	
PURDUE PHARMACEUTICALS L.P.,	)	
THE P.F. LABORATORIES, INC., and	)	
GRÜNENTHAL GmbH,	)	
	)	
Plaintiffs,	)	C.A. No. 15-687 (GMS)
	)	(Consolidated)
v.	)	
	)	
ALVOGEN PINE BROOK, LLC, and	)	
ACTAVIS LABORATORIES FL, INC.,	)	
	)	
Defendants.	)	

**JOINT CLAIM CONSTRUCTION CHART**

Pursuant to the Court’s Scheduling Order (D.I. 22) and the Stipulation and [Proposed] Order to Extend Time filed on June 7, 2016 (D.I. 88) and ordered on June 15, 2016, the parties in the above captioned matter submit their Joint Claim Construction Chart for certain claim terms in U.S. Patent Nos. 6,733,783 (“the ‘783 patent”), 8,361,499 (“the ‘499 patent”), 8,551,520 (“the ‘520 patent”), 8,647,667 (“the ‘667 patent”), 9,023,401 (“the ‘401 patent”), 8,309,060 (“the ‘060 patent”), 8,529,948 (“the ‘948 patent”), and 8,808,740 (“the ‘740 patent”), 9,056,052 (“the ‘052 patent”), 9,060,940 (“the ‘940 patent”), 9,084,816 (“the ‘816 patent”), 9,095,614 (“the ‘614 patent”), 9,095,615 (“the ‘615 patent”), 9,198,863 (“the ‘863 patent”) and 9,205,056 (“the ‘056 patent”). A copy of the Joint Claim Construction Chart is attached as Exhibit A.<sup>1</sup>

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<sup>1</sup> Defendants’ position is that their proposed constructions and intrinsic evidence (if any) herein shall not be construed or interpreted, and shall not work, operate or be urged or deemed in any way, as an admission by Defendants that any claim or claim limitation of the patents-in-suit is in compliance with the requirements of 35 U.S.C. §§ 101, 102, 103, or 112 or as a waiver by any Defendant of its right to assert in this action that any claim of the patents-in-suit is invalid for failure to comply with the requirements of 35 U.S.C.

During the meet and confer process, the parties reached an agreement on the construction of the claim terms set forth in Section I of the attached chart. The parties jointly and respectfully submit that, if the Court deems it appropriate, the Court include these agreed-upon constructions in the ultimate claim construction order. In the alternative, the parties agree that these agreed-upon constructions are binding between the parties.

Section II of the attached chart includes the parties' proposed constructions of the disputed claim terms with citations to the intrinsic evidence in support of their respective proposed constructions. The parties have made a good-faith effort to include herein all known support for their respective constructions, but reserve the right to supplement the attached chart with additional intrinsic evidence and to rely on such evidence in their claim construction briefs.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Rodger D. Smith II*

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Jack B. Blumenfeld (#1014)  
Rodger D. Smith II (#3778)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200  
jblumenfeld@mnat.com  
rsmith@mnat.com

*Attorneys for Plaintiffs*

PROCTOR HEYMAN ENERIO LLP

*/s/ Dominick T. Gattuso*

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Dominick T. Gattuso (#3630)  
300 Delaware Ave., Suite 200  
Wilmington, DE 19801  
(302) 472-7300  
dgattuso@proctorheyman.com

*Counsel for Defendant Alvogen Pine Brook,  
LLC*

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§§ 101, 102, 103, or 112. Plaintiffs' position is that all claims and claim limitations of the patents-in-suit are valid and otherwise in compliance with the requirements of 35 U.S.C. §§ 101, 102, 103, or 112.

OF COUNSEL:

Jeffrey I.D. Lewis  
Justin M. Ross  
Naz Wehrli  
Samuel A. Matthias  
FRIED FRANK HARRIS SHRIVER  
& JACOBSON LLP  
One New York Plaza  
New York, NY 10004  
(212) 859-8000

Shaun Gates  
FRIED FRANK HARRIS SHRIVER  
& JACOBSON LLP  
801 17<sup>th</sup> Street, NW  
Washington, DC 20006  
(202) 639-7000

*Attorneys for Plaintiffs Purdue Pharma L.P.,  
Purdue Pharmaceuticals L.P. and The P.F.  
Laboratories, Inc.*

Basil J. Lewris  
Jennifer H. Roscetti  
Anthony C. Tridico  
Matthew J. Luneack  
Erin M. Sommers  
FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, LLP  
901 New York Avenue, NW  
Washington, DC 20001-4413  
(202) 408-4000

*Attorneys for Plaintiff Grünenthal GmbH*

August 1, 2016

OF COUNSEL:

Matthew J. Becker  
Jeremy Lowe  
Stacie L. Ropka  
AXINN, VELTROP & HARKRIDER LLP  
90 State House Square  
Hartford, CT 06103  
(860) 275-8100

Joshua S. Reisberg  
AXINN, VELTROP & HARKRIDER LLP  
114 West 47<sup>th</sup> Street  
New York, NY 10036  
(212) 728-2200

*Counsel for Defendant Alvogen Pine Brook,  
LLC*

YOUNG CONAWAY STARGATT &  
TAYLOR, LLP

*/s/ Robert M. Vrana*

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Melanie K. Sharp (No. 2501)  
Robert M. Vrana (No. 5666)  
1000 North King Street  
Wilmington, DE 19801  
(302) 571-6681  
msharp@ycst.com

*Counsel for Actavis Laboratories FL, Inc.*

**SECTION I**  
(Agreed Upon Constructions)

**Agreed Upon Constructions**

<b>Claim Term</b>	<b>Agreed Upon Joint Construction</b>
<p>“First administration”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘520:</b> 8, 12, 18</p>	<p>A single dose of the dosage form at the initiation of therapy to an individual patient or a patient population.</p>
<p>“A therapeutic range but below toxic concentration”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘052:</b> 18</p> <p><b>Oshlack ‘401:</b> 17</p>	<p>The parties disagree as to whether this term is indefinite. To the extent the term can be construed, however, the parties agree that it should be construed as follows:</p> <p>Therapeutic blood plasma concentration without clinically unacceptable side effects</p>
<p>“An analgesically effective amount”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘783:</b> 2, 7, 16, 17</p> <p><b>Oshlack ‘499:</b> 3, 4, 7, 8, 12</p> <p><b>Oshlack ‘520:</b> 8, 12</p> <p><b>Oshlack ‘667:</b> 8, 12</p> <p><b>Oshlack ‘940:</b> 20</p>	<p>The parties disagree as to whether this term is indefinite. To the extent the term can be construed, however, the parties agree that it should be construed as follows:</p> <p>The amount of drug required to cause pain relief in a patient</p>
<p>“Therapeutic plasma concentration”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘499:</b> 3</p>	<p>The parties disagree as to whether this term is indefinite. To the extent the term can be construed, however, the parties agree that it should be construed as follows:</p> <p>Blood plasma concentration of active ingredient sufficient to cause pain relief</p>

Claim Term	Agreed Upon Joint Construction
<p>“Melting point”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘499:</b> 8</p> <p><b>Oshlack ‘520:</b> 8</p> <p><b>Oshlack ‘667:</b> 8</p>	<p>Temperature at which the liquid and solid phases exist in equilibrium</p>
<p>“Dissolution release rate”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘783:</b> 7</p>	<p>The amount of drug released from a dosage form, per unit of time, into a laboratory apparatus</p>
<p>“In-vitro release rate”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘499:</b> 3, 4, 7, 8, 12</p> <p><b>Oshlack ‘520:</b> 8, 12, 18</p> <p><b>Oshlack ‘667:</b> 8, 12, 16, 20, 26, 27</p>	<p>The amount of drug released from a dosage form, per unit of time, into a laboratory apparatus</p>

Claim Term	Agreed Upon Joint Construction
<p>“Only active agent”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘667:</b> 8, 12, 16, 20, 26, 27</p> <p><b>Oshlack ‘401:</b> 22, 28</p> <p><b>Oshlack ‘052:</b> 23, 30</p> <p><b>Oshlack ‘863:</b> 5, 6, 7, 13, 28</p> <p><b>Oshlack ‘056:</b> 13, 17, 28</p>	<p>Lone pharmacological active ingredient</p>
<p>“Abuse-proofed”</p> <p><u>Claim(s)</u></p> <p><b>Bartholomaeus ‘060:</b> 1</p>	<p>A reduction in the potential for abuse</p>
<p>“Tampering by crushing and dissolution”</p> <p><u>Claim(s)</u></p> <p><b>Wright ‘948:</b> 21</p>	<p>Process of making the active ingredient available for inappropriate use by means of deforming or pulverizing the dosage form and dissolving it</p>
<p>“Weight ratio of the core”</p> <p><u>Claim(s)</u></p> <p><b>Huang ‘740:</b> 10</p>	<p>Ratio of total weight of the core to the total weight of the shell</p>

## **SECTION II**

(Disputed Constructions)



**Disputed Constructions**

<b>Claim Term</b>	<b>Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence</b>	<b>Defendants' Proposed Construction and Citations to Intrinsic Evidence<sup>1</sup></b>
<p>"Controlled release material"</p> <p><u>Claim(s)</u></p> <p><b>Oshlack '783:</b> 2, 7, 16, 17</p> <p><b>Oshlack '499:</b> 3, 4, 7, 8, 12</p> <p><b>Oshlack '520:</b> 8, 12, 18</p> <p><b>Oshlack '667:</b> 8, 12, 16, 20, 26, 27</p> <p><b>Oshlack '401:</b> 22, 28</p> <p><b>Oshlack '052:</b> 23, 30</p> <p><b>Oshlack '940:</b> 20</p>	<p>A material incorporated into and forming the matrix of a dosage form that results in the release of active ingredient at controlled rates</p> <p><u>Citations to Intrinsic Evidence:</u> '783, 3:47-52; '499, 3:53-58; '520, 3:53-58; '667, 3:56-61; '401, 3:62-67; '052, 3:62-67; '940, 3:56-61.</p> <p>'783, 6:61-7:3; '499, 6:65-7:4; '520, 6:65-7:4; '667, 6:66-7:5; '401, 7:7-13; '052, 7:7-13; '940, 6:66-7:5.</p> <p>'940, 26:4-5.</p>	<p>A pharmaceutical excipient that functions to substantially increase the duration of release of the drug substance compared to an immediate release formulation</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'783 patent, 1:31-35,<sup>2</sup> 7:38-41, 11:50-54, Abstract, 1:46-55, 6:61-7:1, 7:19-31, 3:47-52, 1:31-35, 3:4-11, 4:26-31, 6:11-20, 10:61-11:1, 13:12-24, 14:45-54, 15:10-14, 15:36-38, 15:49-54, 18:53-58, 18:59-63, 18:66-19:1, 19:33-36, 19:64-20:8, 20:66-21:4.</p> <p>U.S. Patent No. 5,958,452 ("the '452 patent"), 6:36-38, 11:33-40, 5:25-31.</p> <p>U.S. Patent No. 5,958,459 ("the '459 patent"), 7:66 – 8:2, 1:18-24.</p>
<p>"Matrix"</p> <p><u>Claim(s)</u></p>	<p>Pharmaceutical preparation that incorporates a dispersed/embedded active ingredient/agent</p>	<p>A discrete solid structure in which the drug is dispersed or embedded</p>

<sup>1</sup> Plaintiffs and Defendants reserve the right to rely on the entire intrinsic record, including any portion of the specification, prosecution history and intrinsic prior art references cited therein, to support or rebut proposed claim construction positions. Plaintiffs and Defendants may also rely on intrinsic and extrinsic evidence identified by any party in support of their constructions; on expert testimony to rebut Plaintiffs' and Defendants' proposed meanings; and on expert testimony or other evidence, if any, offered by any party in support of their own claim constructions.

<sup>2</sup> Unless otherwise noted, all references to the '783, '499, '520, '667, '401, '052, '940, '863 and '056 patents ("the Oshlack patents") will be to the '783 patent. The Oshlack patents share a common genealogy and include a substantially similar specification.

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
<b>Oshlack '783:</b> 2, 7, 16 <b>Oshlack '499:</b> 7, 8, 12 <b>Oshlack '520:</b> 8, 12, 18 <b>Oshlack '667:</b> 8, 12, 16, 20, 26, 27 <b>Oshlack '052:</b> 23, 30 <b>Oshlack '056:</b> 13,17, 28 <b>Huang '740:</b> 7-11, 13, 15, 20, 72 <b>McKenna '816:</b> 18, 27, 28 <b>McKenna '614:</b> 18, 26 <b>McKenna '615:</b> 6, 14, 27	<u>Citations to Intrinsic Evidence:</u> '783, 6:61-66; '499, 6:65-7:3; '520, 6:65-7:3; '667, 6:66-7:4; '401, 7:7-12; '052, 7:7-12; '056, 7:10-15. '783, 7:7-13; '499, 7:11-16; '520, 7:11-16; '667, 7:12-17; '401, 7:20-25; '052, 7:20-25; '056, 7:23-28. '783, 7:19-22; '499, 7:22-25; '520, 7:22-25; '667, 7:23-26; '401, 7:31-34; '052, 7:31-34; '056, 7:34-337. '056, 25:24-31. Encarta 2006 for "matrix" definition (Cited in '499, '520, '667, '052, '056 patents) <sup>3</sup> . '740, 2:38-49. '740, 4: 1-8. '740, 11:48-58. US Patent No. 4,366,310, 1:4-11 (cited in '740 patent). '816, 2:27-37; '614, 2:28-38; '615, 2:27-37. '816, 2:41-52, '614, 2:42-53; '615: 2:41-52. <u>McKenna</u> , 6/29/2006 Response in 10/214,412 at p.9. <u>McKenna</u> , 6/29/2006 Response in 10/214,412 at p.10. U.S. Patent No. 4,629,621, 2:41-45 (cited in '816, '614 and '615 patents)	<u>Citations to Intrinsic Evidence:</u> '783 patent, 7:19-22, 6:61-66, 6:14-15, 6:39-41, 2:41-44, 2:44-45, 2:51-52, 6:61-64, 10:34-42, 9:11-18, 2:53-59. '740 patent, Abstract, 2:39-44, 3:59-64, 4:3-7, 11:17-22, 14:65-15:17. '060 patent, 16:4-10, 16:17-19.  U.S. Patent No. 5,968,551, 1:35-40.

<sup>3</sup> Prior art listed as a reference on the face of a patent constitutes intrinsic evidence. *See V-Formation, Inc. v. Benetton Group SPA etc.*, 401 F.3d 1307, 1311 (Fed. Cir. 2005) ("The Meibock patent is prior art that was listed as a reference on the face of the '466 patent and in an Information Disclosure Statement. This prior art reference to Meibock is not extrinsic evidence.")

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
	<p>U.S. Patent No. 4,690,822, 1:19-28 (cited in '816, '614 and '615 patents)</p> <p>U.S. Patent No. 5,273,758, 4:9-13 (Discussed in <u>Huang</u>, 1/27/13 Office Action at p. 3-6 and 4/29/13 Response in 13/333,560 at p. 18-20; <u>McKenna</u>, 11/20/2014 Office Action at p. 3-6 and 2/20/2015 Response in 14/515,924 at p. 8-10; <u>McKenna</u>, 11/28/2014 Office Action at p. 5-6 and 2/20/2015 Response in 14/515,855 at p. 8-10; <u>McKenna</u> 11/21/2014 Office Action at p. 3-5 and 2/20/2015 Response in 14/515,921 at 8-10).</p> <p>U.S. Patent No. 5,215,758, 6:17-23 (Discussed in <u>Huang</u>, 1/27/13 Office Action at p. 3-6 and 4/29/13 Response in 13/333,560 at p. 18-20; <u>McKenna</u>, 11/20/2014 Office Action at p. 3-6 and 2/20/2015 Response in 14/515,924 at p. 8-10; <u>McKenna</u>, 11/28/2014 Office Action at p. 5-6 and 2/20/2015 Response in 14/515,855 at p. 8-10; <u>McKenna</u> 11/21/2014 Office Action at p. 3-5 and 2/20/2015 Response in 14/515,921 at 8-10).</p>	
<p>"Matrices"</p> <p><u>Claim(s)</u></p> <p><b>Oshlack '401: 22, 28</b></p>	<p>Plural of "Matrix" [i.e., Pharmaceutical preparation that incorporates a dispersed/embedded active ingredient/agent]</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'401, 9:46-47.</p> <p>'783, 25:34-37.</p>	<p>More than one discrete solid structure in which the drug is dispersed or embedded</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p><i>See above</i></p>

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
<p>“Matrix”</p> <p><u>Claim(s)</u></p> <p><b>Bartholomaus ‘060:</b> 23, 24</p>	<p><i>See</i> “controlled release matrix material” below</p>	<p><u>Defendants' Proposed Construction:</u></p> <p>Same construction of “matrix” as above.</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>‘060 patent, 16:4-10, 16:17-19.</p>
<p>“Controlled release matrix material”</p> <p><u>Claim(s)</u></p> <p><b>Huang ‘740:</b> 7-11, 13, 15, 20, 72</p> <p><b>Bartholomaus ‘060:</b> 24</p>	<p>The material or materials in which the active ingredient is embedded that also serve(s) to control the release of the active ingredient from the dosage form</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>‘740, 2:38-49.</p> <p>‘740, 4:1-8.</p> <p>‘740, 11:48-58.</p> <p>‘740, 47:50- 48:4.</p> <p>‘740, 14:56- 15:17.</p> <p>’060, claims 22-24.</p> <p>’060, 16:4-67; 17:1 – 21:3.</p> <p>Portions from the prosecution history of U.S. Patent No. 8,114,383:</p> <p>Application No. 10/718,112, Response to Office</p>	<p>A pharmaceutical excipient located within a discrete solid structure in which the drug is dispersed or embedded that functions to substantially increase the duration of release of the drug substance compared to an immediate release formulation</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>‘740 patent, Abstract, 2:39-44, 3:59-64, 4:3-7, 11:17-22, 14:65-15:17, 11:47-53, 15:13-17.</p> <p>‘060 patent, 16:4-10, 16:17-25.</p>

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
	<p>Action dated December 28, 2006 (GRT00259574-90, GRT00259615) including GRT00259576-78, GRT00259581;</p> <p>Application No. 10/718,112, Response dated July 30, 2009 (GRT00260914-27) including GRT00260920-26;</p> <p>Application No. 10/718,112, Response dated May 18, 2010 (GRT00264291-337) including GRT00264300-05;</p> <p>Application No. 10/718,112, Response dated October 26, 2010 (GRT00264383-98) including GRT00264391-96.</p>	
<p>“Steady state”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘667:</b> 8, 12, 16, 20, 26, 27</p>	<p>A state in which the amount of drug reaching blood serum is approximately the same as the amount of drug leaving blood serum</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>‘667, 4:48-52.</p>	<p><u>Defendants' Proposed Construction:</u></p> <p>“The amount of the drug reaching the system is approximately the same as the amount of the drug leaving the system”</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>‘667 patent, 4:47-49, 4:49-52.</p>
<p>“A <math>C_{24}/C_{max}</math> ratio”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘783:</b> 2, 7, 16, 17</p>	<p>Ratio of blood plasma concentration of the active ingredient 24 hours after administration of the dosage form to the highest plasma concentration of the active ingredient attained within the dosing interval (here 24 hours)</p>	<p>The ratio of the plasma concentration of the drug at 24 hours after administration to the highest plasma concentration of the drug attained within the dosing interval</p>

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
<b>Oshlack '499:</b> 3, 4, 7, 8, 12 <b>Oshlack '520:</b> 8, 12 <b>Oshlack '667:</b> 8, 12, 16, 20, 26, 27 <b>Oshlack '940:</b> 20	<u>Citations to Intrinsic Evidence:</u> '783, 3:63-67; '499, 4:1-4; '520, 4:1-4; '667, 4:4-7; '940, 4:4-7. <b>11/17/2008 Notice of Allowability p.3.</b>	<u>Citations to Intrinsic Evidence:</u> '783 patent at 3:64-67. '360 patent, 14:37-49.
"C <sub>24</sub> /C <sub>max</sub> hydrocodone ratio"  <u>Claim(s)</u> <b>Oshlack '863:</b> 5, 6, 7, 13 <b>Oshlack '056:</b> 13, 17	Ratio of blood plasma concentration of hydrocodone 24 hours after administration of the dosage form to the highest plasma concentration of hydrocodone attained within the dosing interval (here 24 hours)  <u>Citations to Intrinsic Evidence:</u> '863, 4:13-16; '056, 4:13-16. '863, 3:63-64, 3:66-67; '052, 3:63-64, 3:66-67.	The ratio of the plasma concentration of the drug at 24 hours after administration to the highest plasma concentration of the drug attained within the dosing interval  <u>Citations to Intrinsic Evidence:</u> '863 patent at 4:13-16. '360 patent, 14:37-49.
"A relatively flat serum plasma profile"  <u>Claim(s)</u> <b>Oshlack '499:</b> 3, 4, 7, 8, 12	When displayed graphically, the amount of active ingredient in the blood plasma from a controlled release formulation, over the period of time that the C <sub>24</sub> /C <sub>max</sub> ratio is between about 0.55 to about 1.0 and the patient experiences effective pain relief, is relatively flat as compared with the amount of active ingredient in the blood plasma from dosings of an immediate release formulation over the same time period  <u>Citations to Intrinsic Evidence:</u>	The plasma level of the drug provides a C <sub>24</sub> /C <sub>max</sub> ratio of about 0.55 to about 1.0  <u>Citations to Intrinsic Evidence:</u> '499 patent, 1:49-52.  File History of '499 patent (PHY004354-4502), Examiner Initiated Interview, Sept. 28, 2012 at 1 (PHY004467), Examiner Reasons for Allowance, Sept. 28, 2012 at 3 (PHY004469).

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
	'499, 1:45-53.	
<p>“Obtaining a serum profile”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘940: 20</b></p>	<p>Establishing a blood plasma serum profile in a patient</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'940, 1:41-49.</p> <p>'940, 2:25-30.</p> <p><u>Oshlack</u>, 3/17/2014 Preliminary Amendment at p. 7.</p> <p>'520, 25:38-44.</p> <p>'667, 25:45-50.</p>	<p>Construction not necessary. To the extent the term requires construction, the construction should be:</p> <p>“assaying serum samples to obtain a profile”</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'940 patent, 4:49-52.</p>
<p>“Thermoformed dosage form”</p> <p><u>Claim(s)</u></p> <p><b>Bartholomaus ‘060: 1</b></p>	<p>A dosage form made using pressure with preceding, simultaneous, or subsequent heat so as to achieve the claimed breaking strength</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'060 patent claim 1, claim 25, claim 27.</p> <p>'060, 1:33-45; 2:4-42; 11:13-45; 17:35 – 21:3.</p> <p>Portions from the prosecution history of U.S. Patent No. 8,114,383:</p> <p>Originally filed Application No. 10/718,112 and claims (GRT00258648-88, GRT00258697-750) including GRT00258743, GRT00258749;</p>	<p>A dosage form that is formed by the application of pressure to the components with the simultaneous or preceding application of heat</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'060 patent at Abstract, 1:16-17, 2:17-18, 11:13-19, 11:25-40, Example 1 at 17:60-66, Example 6 at 20:27-28, Example 2 at 18:28-31, Example 3 at 18:47-52, Example 4 at 19:15-22, Example 5 at 19:61-67, 1:6-10,</p> <p>File history of U.S. Patent No. 8,114,383 (“the ‘383 patent”) (GRT147606-9181), Nov. 27, 2006 Response to Office Action dated July 25, 2006, at 11 (GRT00147674), May 29, 2007 Response to</p>

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
	<p>Application No. 10/718,112, Response to Office Action dated July 25, 2006 (GRT00259486-503) including GRT00259495-96;</p> <p>Application No. 10/718,112, Response to Office Action dated December 28, 2006 and Declaration of Dr. Johannes Bartholomäus dated May 3, 2007 (GRT00259574-615) including GRT00259574-75, GRT00259587-88;</p> <p>Application No. 10/718,112, Amendment dated July 5, 2011 (GRT00264460, GRT00264549-64) including GRT00264549-52;</p> <p>Application No. 10/718,112, Response dated May 18, 2010 (GRT00264291-337) including GRT00264298;</p> <p>Application No. 10/718,112, Response dated January 16, 2008 (GRT00260724-35) including GRT00260725-26;</p> <p>Application No. 10/718,112, Amendment dated February 17, 2009 (GRT00260763-77) including GRT00260764</p>	<p>Office Action dated Dec. 28, 2006 at 6 (GRT00147710), 13-14 (GRT00147717-8).</p>
<p>“Breaking strength of at least 500 N”</p> <p><u>Claim(s)</u></p>	<p>The dosage form may undergo plastic deformation when force is applied to it, but requires at least 500 Newtons of force to break, namely, to separate into two or more pieces</p>	<p>Only separates into two or more pieces when exposed to a force of at least 500 newtons</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>‘060 Patent, 1:33-35, 2:26-42, 5:54 – 6:9, Example</p>



Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
<b>Bartholomaus '060: 1</b>	<u>Citations to Intrinsic Evidence:</u> '060 patent, claim 1.  '060, 1:26-49; 2:4-45; 5:54 – 6:34; 17:1 – 21:3.  Portions from the prosecution history of U.S. Patent No. 8,114,383:  Application No. 10/718,112, Response dated October 26, 2010 (GRT00264383-98) including GRT00264396-97.	1 at 18:1-3, Example 3 at 18:53-55, Example 4 at 19:23-26, Example 5 at 20:1-4, Example 6 at 20:61-63, 17:24-26.
“Viscosity-increasing agent”  <u>Claim(s)</u> <b>Bartholomaus '060: 9</b>	A substance that increases the resistance of a fluid to flow  <u>Citations to Intrinsic Evidence:</u> '060 patent, claim 1, claim 9, claim 15, claim 21, and claim 24.  '060 patent, 2:15-45; 5:54 – 11:45; 16:17-47; 17:35 – 21:3.	At least one substance that increases the thickness of the dosage form by forming a gel when exposed to a liquid, said substance being different from the synthetic or natural polymer (C) of 1 of the '060 patent  <u>Citations to Intrinsic Evidence:</u> '060 patent, 8:24-34, 6:35-53, 6:54-60, 8:19-54, 8:63 – 9:18, 9:23-30, 9:31-34, 16:17-24, 17:35 – 21:3.
“Necessary minimum quantity of an aqueous liquid”  <u>Claim(s)</u>	10 ml of water at a temperature of 25° C  <u>Citations to Intrinsic Evidence:</u> '060 patent, claim 9.	This term is indefinite. To the extent this term can be construed, it should be construed as:  “an aqueous liquid in a necessary minimum quantity”  The claim is nevertheless indefinite.

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
<b>Bartholomaus '060:</b> 9	'060 patent, 8:22-24; 8:55-62; 19:1 – 21:3.	<u>Citations to Intrinsic Evidence:</u> '060 patent, 1:33-39, 6:35-53, 8:19-27, 9:23-30, 19:1 – 21:3.
<p>“Combining said [opioid/hydrocodone] or pharmaceutically acceptable salt thereof with each of said low molecular weight polyethylene oxide and said high molecular weight polyethylene oxide to form at least one blend”</p> <p><u>Claim(s)</u></p> <p><b>McKenna '816:</b> 18, 27, 28</p> <p><b>McKenna '614:</b> 18, 26</p> <p><b>McKenna '615:</b> 6, 14, 27</p>	<p>Forming at least one blend of (a) low molecular weight polyethylene oxide with hydrocodone and high molecular weight polyethylene oxide with hydrocodone separately, or (b) low molecular weight polyethylene oxide and high molecular weight polyethylene oxide with hydrocodone together, done either as a separate blending step or during the formation of the shaped tablet prior to curing</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'615, 168:16-20.</p> <p><u>McKenna</u> 6/29/2006 Response in 10/214,412 at p.10.</p> <p><u>McKenna</u> 2/20/15 Response in 14/515,921 at p. 6.</p> <p><u>McKenna</u> 2/20/15 Response in 14/515,921 at p. 8.</p> <p>U.S. Patent No. 8,911,719, 163:33-164:55 (Terminally disclaimed over '816, '614, and '615 patents).</p>	<p>“forming at least one blend comprising said opioid or pharmaceutically acceptable salt thereof, said low molecular weight polyethylene oxide, and said high molecular weight polyethylene oxide”</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'816 patent, 2:41-52,<sup>4</sup> 5:45-57, 29:19-31, Example 4 at 45:1-35, 46:1-4, Example 5 at 53:21-50, 53:51 – 54:28, Example 7 at 59:40-66, 60:1-23, Example 8 at 66:37-55, 66:57-65, Example 25 at 137:27-59, 137:59 – 138:14.</p>
“A gelling agent comprising polyethylene	A composition used to impart gel-like or thickening quality to a tampered dosage form upon addition of	Construing only <i>italicized section</i>

<sup>4</sup> Unless otherwise noted, all references to the '816, '615, and '614 patents (“the McKenna patents”) will be to the '816 patent. The McKenna patents share a common genealogy and include a substantially similar specification.

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
<p>oxide in an effective amount to impart <i>viscosity of at least about 10 cP when the dosage form is subjected to tampering by dissolution in from about 0.5 to about 10 ml of an aqueous solution</i>"</p> <p><u>Claim(s)</u></p> <p><b>Wright '948:</b> 7, 10, 15, 21, 22</p>	<p>moisture or liquid and the resulting solution's viscosity is measured by the syringe method of Example 3 where it is hard to fill an insulin syringe with solutions of 10 cP to 60 cP</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'948, 5:20-24.</p> <p>'948 patent, 3:9-22.</p> <p>'948, 40:56-61.</p> <p><b>11/1/2004 Office Action SN 10/214,412 at pp. 7-8.</b></p> <p><b>5/2/2005 Response SN 10/214,412 at p. 11 (emphasis in original).</b></p> <p><b>5/2/2005 Response SN 10/214,412 at p. 12 (emphasis in original).</b></p> <p><b>7/18/2005 Office Action SN 10/214,412 at p. 7.</b></p> <p><b>7/5/2007 Response SN 10/214,412 at p. 9.</b></p> <p>1/18/2006 Response SN 10/214,412 at pp.9-10.</p> <p><b>6/29/2006 Response SN 10/214,412 at p. 10.</b></p> <p><b><u>Wright</u> 7/12/2011 Office Action SN 12/653,115 at p.3.</b></p>	<p>This term is indefinite. To the extent this term can be construed, it should be construed as:</p> <p>"dissolving the dosage form in from about 0.5 to about 10 ml of an aqueous solution, causing the resulting mixture to have a viscosity of at least about 10 cP"</p> <p>The claim is nevertheless indefinite.</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'948 patent, 2:46-51, 2:22-30, 2:60-67, 3:1-27, 5:27-37, 7:22-28, 7:29-35, 42:19-22.</p>
<p>"Viscosity of at least about 60 cP"</p> <p><u>Claim(s)</u></p>	<p>Viscosity as measured by the syringe method of Example 3 where one cannot fill an insulin syringe with solutions of 60 cP or more without picking up large pockets of air</p>	<p>This term is indefinite. To the extent this term can be construed, it should be construed as:</p> <p>"dissolving the dosage form in from about 0.5 to about 10 ml of an aqueous solution, causing the resulting mixture to have a viscosity of at least</p>

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
<b>Wright '948: 7</b>	<u>Citations to Intrinsic Evidence:</u> '948, 7:22-28. '948, Table 3 '948, 40:56-61. <b>10/1/2012 Amendment SN 13/349, 449 at pp. 6-7:</b>	about 60 cP" The claim is nevertheless indefinite.  <u>Citations to Intrinsic Evidence:</u> <i>See</i> term above.
<p>"Based on rheological measurements, ... molecular weight"<sup>5</sup></p> <p>-----</p> <p>"Molecular weight ... based on rheological measurements"</p> <p><u>Claim(s)</u></p> <p><b>McKenna '816:</b> 18, 27, 28</p> <p><b>McKenna '614:</b> 18, 26</p> <p><b>McKenna '615:</b> 6, 14, 27</p>	<p>A measure of the mass of a molecule [based on] correlation of molecular weight to viscosity according to rheological measurements</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'816, 7:52-8:30; '614, 7:59-8:39; '615, 7:56-8:36.</p> <p><u>McKenna</u>, Declaration of Richard O. Mannion Under 37 C.F.R. dated 3/27/2015 for 14/515,857 at 1-2.</p> <p>Wright, 2003/0068375 at p. 13 paragraph 150 (Discussed in <u>McKenna</u>, 11/28/2014 Office Action at p. 5-6 and 2/20/2015 Response in 14/515,855 at p. 8-10).</p> <p>U.S. Patent No. 5,273,758, 1:64-2:23 (Discussed in <u>McKenna</u>, 11/20/2014 Office Action at p. 3-6 and 2/20/2015 Response in 14/515,924 at p. 8-10; <u>McKenna</u>, 11/28/2014 Office Action at p. 5-6 and</p>	<p><u>Defendants' Proposed Construction:</u></p> <p>This term is indefinite. To the extent this term can be construed, it should be construed as:</p> <p>"A measure of the mass of a molecule [based on] a measurement of the change in form and the flow of matter."</p> <p>The claim is nevertheless indefinite.</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'816 patent, 6:36-43, 7:44-49, 7:50 –8:26, 8:27-30, 23:61 – 24:3, 24:4-17, 24:18-27, 24:38-48, 28:5-8, 35:18-27.</p> <p><u>See also</u> Citations to Intrinsic Evidence with respect to "Combining said [opioid/hydrocodone] or pharmaceutically acceptable salt thereof . . ." above.</p>

<sup>5</sup> In context, e.g. claim 6 of the '816 patent states "... (2) at least one low molecular weight polyethylene oxide having, based upon rheological measurements, an approximate molecular weight of less than 1,000,000 ..."

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
	<p>2/20/2015 Response in 14/515,855 at p. 8-10; <u>McKenna</u> 11/21/2014 Office Action at p. 3-5 and 2/20/2015 Response in 14/515,921 at 8-10).</p> <p>U.S. Patent No. 5,914,131, 6:27-42 (cited in '816, '614 and '615 patents)</p> <p>U.S. Patent No. 5,914,131, 7:21-31 (cited in '816, '614 and '615 patents)</p> <p>U.S. Patent No. 7,842,307, 27:66-28:51 (cited in '816, '614 and '615 patents)</p>	
<p>"Average molecular weight"</p> <p><u>Claim(s)</u></p> <p><b>Oshlack '863:</b> 6, 7</p> <p><b>Huang '740:</b> 8, 9</p>	<p>Calculating molecular weight of a polymer sample when taking into account the molecular size of each polymer chain rather than just the number of molecules in the sample</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>Oshlack '863, claims 4-5</p> <p>'863, 16:25-42</p> <p>'863, 16:47-57.</p> <p><u>Huang</u> '740, 8:11-18.</p> <p>U.S. Patent No. 5,273,758, 2:64-3:30 (Discussed in <u>Huang</u>, 1/27/13 Office Action at p. 3-6 and 4/29/13 Response in 13/333,560 at p. 18-20).</p> <p>'783, 16:41-51; U.S. Patent No. 7,842,307, 28:27-37 (cited in '740 patent)</p>	<p>This term is indefinite. To the extent this term can be construed, it should be construed as:</p> <p>"the average of the molecular weights"</p> <p>The claim is nevertheless indefinite.</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'863 patent, 9:11-15, 16:16-42, 16:43 – 17:4, 17:49-59, 20:35-49, Example 3 at 24:16-19 and 41-44.</p> <p>'740 patent, 8:4-10, 8:11-14, 8:15-18, 15:30 – 16:3, Example 1 at 28:11-13, Example 2 at 28:52-54; Example 3 at 29:28-30, Example 4 at 30:3-5, Example 5 at 30:46-48, Example 6 at 31:23-25, Examples 7-12 at 32:18-19, 32:28-29, 32:55-56, 32:65-66.</p>

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
<p>“Weight-average molecular weight”</p> <p><u>Claim(s)</u></p> <p><b>Oshlack ‘863: 5, 6</b></p> <p><b>Wright ‘948: 10</b></p>	<p>Calculating molecular weight of a polymer sample when taking into account the molecular size of each polymer chain rather than just the number of molecules in the sample</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>‘863, 16:25-42</p> <p>‘863, 16:47-57.</p> <p>‘948, 23:28-45.</p> <p>‘948 , 23:50-60.</p> <p>U.S. Patent No. 5,866,164, 2:56-62 (cited in ‘948 patent).</p> <p>U.S. Patent No. 5,866,164, 3:49-65 (cited in ‘948 patent)</p> <p>U.S. Patent No. 5,866,164, 5:5-54 (cited in ‘948 patent)</p> <p>U.S. Patent No. 5,866,164, 7:9-12 (cited in ‘948 patent)</p> <p>U.S. Patent No. 6,419,954, 7:3-7 (cited in ‘948 patent)</p>	<p>The weighted average of the molecular weights</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>‘948 patent, 23:22-45, 23:46 – 24:7.</p> <p><u>See above</u> with respect to “average molecular weight.”</p>
<p>“Wherein the polymer (C)</p>	<p>Wherein the polymer (C) has a weight average</p>	<p><u>Defendants' Proposed Construction:</u></p>

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
<p>has a molecular weight of at least 0.5 million according to rheological measurements”</p> <p><u>Claim(s)</u></p> <p><b>Bartholomäus ‘060: 1</b></p>	<p>molecular weight of at least 0.5 million according to rheological measurements</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>’060 patent, claim 1, claims 4-5, claim 30, and claims 33-34.</p> <p>’060, 5:54 – 6:10; 17:1 – 21:3.</p> <p>Portions from the prosecution history of U.S. Patent No. 8,114,383:</p> <p>Application No. 10/718,112, Response to Office Action dated December 28, 2006 and accompanying Declaration of Dr. Johannes Bartholomäus dated May 3, 2007 (GRT00259574-615) including GRT00259587-89, GRT00259609;</p> <p>Application No. 10/718,112, Amendment dated February 17, 2009 and accompanying Declarations of Heinrich Kugelmann dated February 6, 2009 and Dr. Johannes Bartholomäus dated August 25, 2008 (GRT00260763-94) including GRT00260775, GRT00260784, GRT00260786, GRT00260789-90, GRT00260792-93;</p> <p>Application No. 10/718,112, Response dated July 30, 2009 and accompanying Declaration of Heinrich Kugelmann dated July 2, 2009 (GRT00260914-30) including GRT00260928-29;</p> <p>Application No. 10/718,112, Response dated May 18, 2010 (GRT00264291-337) including</p>	<p>This term is indefinite. To the extent this term can be construed, it should be construed as:</p> <p>“Wherein the mass of the molecules of polymer (C) is at least 0.5 million according to measurements based on the change in form and the flow of matter”</p> <p>The claim is nevertheless indefinite.</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>’060 patent, 5:54 – 6:9.</p>

Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
	<p>GRT00264312-15;</p> <p>Application No. 10/718,112, Amendment dated July 5, 2011 (GRT00264460, GRT00264549-64) including GRT00264561-62;</p> <p>Application No. 10/718,112, Amendment dated September 8, 2011 (GRT00269504-08) including GRT00269504-05.</p> <p>Portions from the prosecution history of U.S. Patent No. 8,309,060:</p> <p>Application No. 13/346,257, Notice of Allowance and Examiner's Amendment dated October 9, 2012 (PHY00004325-29) including PHY00004327-28.</p>	
<p>"A shell encasing the core"</p> <p><u>Claim(s)</u></p> <p><b>Huang '740:</b> 7, 8, 9, 10, 11, 13, 15, 20, 72</p>	<p>Core- a central and often foundational part usually distinct from the enveloping part by a difference in nature</p> <p>Shell- a layer or surface enclosing a space or surrounding an object</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'740, 2:38-44.</p> <p>'740, 10:56-59.</p> <p>'740, 11:23-31.</p> <p>'740, 16:16-53.</p> <p>'740, 28:26-31.</p>	<p><u>Defendants' Proposed Construction:</u></p> <p>"The outer layer of the dosage form surrounding the core"</p> <p><u>Citations to Intrinsic Evidence:</u></p> <p>'740 patent at Abstract, Examples at 28:8 – 47:32, Examples 1-6 at 28:8 – 31:61, Examples 7-12 at 31:62 – 34:39, Examples 14-20 at 39:37 – 43:20, 10:53-65.</p> <p>The file history of the '740 patent (PHY00000001-2374), Amendment and Response, April 29, 2013, at 17-19 (PHY00000790-92).</p>



Claim Term	Plaintiffs' Proposed Construction and Citations to Intrinsic Evidence	Defendants' Proposed Construction and Citations to Intrinsic Evidence <sup>1</sup>
	Huang 4/29/2013 Amendment SN 13/333,560 at pp. 17-18.	

### Other Terms

The following terms do not require independent construction, in the opinion of the Parties, but rather will follow the construction of terms in dispute.

Claim Term	Construction
<p>“Wherein the controlled release material is incorporated into a matrix”</p> <p><u>Claim(s)</u> <b>Oshlack ‘499:</b> 7, 8, 12</p>	<p><i>See</i> above for “controlled release material” and “matrix.” No further construction is needed except for the terms referenced above.</p>
<p>“Controlled release matrix formulation”</p> <p><u>Claim(s)</u> <b>Oshlack ‘783:</b> 17</p>	<p><i>See</i> above for “controlled release material” and “matrix.” No further construction is needed for “formulation.”</p>
<p>“Amount of a controlled release material sufficient to render”</p> <p><u>Claim(s)</u> <b>Oshlack ‘520:</b> 8, 12, 18</p>	<p><i>See</i> above for “controlled release material.” No further construction is needed except for “controlled release material.”</p>

Claim Term	Construction
Oshlack ‘667: 8, 12, 16, 20, 26, 27	